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TC 1700

Docket No. 071949-1315

Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Kenneth F. Buechler

Serial No.: 09/982,629

Filed: October 18, 2001

For: DIAGNOSTIC DEVICES AND
APPARATUS FOR THE
CONTROLLED MOVEMENT OF
REAGENTS WITHOUT
MEMBRANES

Examiner: Alexander, Lyle

Group Art Unit: 1743

<p>CERTIFICATE OF MAILING</p> <p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, Alexandria, VA 22313-1450, on the date below.</p> <p><u>Germaine Sarda</u> (Printed Name)</p> <p><u><i>Germaine Sarda</i></u> (Signature)</p> <p><u>October 17, 2003</u> (Date of Deposit)</p>
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DECLARATION OF DR. KENNETH F. BUECHLER

I, Kenneth F. Buechler, Ph.D., being duly warned that willful false statements and the like are punishable by fine or imprisonment or both (18 U.S.C. § 1001), and may jeopardize the validity of the patent application or any patent issuing thereon, state and declare as follows:

1. All statements herein made of my own knowledge are true, and statements made on information or belief are believed to be true and correct.

2. I am currently Sr. Vice President of Research and Development for Biosite Incorporated, San Diego, CA, the assignee of U.S. Patent Application No. 09/982,629 ("the '629 application"). I am named as sole inventor on the '629 application. A copy of my curriculum vitae is attached to my declaration.

3. I have reviewed and am familiar with the specification filed in the '629 application, the most recent Office Action mailed on July 22, 2003, and U.S. Patent No. 5,202,268 ("the '268 patent"), cited by the Examiner in the Office Action.

4. The claims pending in the '629 application all refer to devices comprising one or more "capillary channels," that is, a channel through which fluid is drawn by capillarity. It is my opinion that the skilled artisan would interpret the term "channel" to refer to a discrete enclosed passage through which fluid flows. A "capillary channel" would not include the random, tortuous flow path existing through a porous material. This interpretation is based on the common meaning of the term "channel" in the art, and on the distinctions drawn in the '629 application.

5. Merriam Webster's Collegiate Dictionary, 10th Edition, refers to a number of meanings for the term "channel." For purposes of the present claims, the relevant meaning is "a usually tubular enclosed passage: CONDUIT." This definition is consistent with the use of the term "channel" in the present specification. For example, the specification states on page 7, lines 30-32, that the assay devices comprise two surfaces disposed a capillary distance apart; and on page 8, lines 25-29, that the capillary channels are formed when a top member and a bottom member are placed a capillary distance apart. The specification indicates that, while a tubular enclosed passage may be used as a channel (*e.g.*, page 25, lines 3-7), the channel may also be formed using relatively parallel surfaces.

6. In contrast, the '268 patent relies on flow paths through a porous material, such as a glass fiber or polymer material, a paper, *etc.* See, *e.g.*, '269 patent, column 3, lines 52-59. One of ordinary skill in the art would understand that flow through such a porous material is random, as any particular portion of the fluid volume need not traverse the same path as another portion of the fluid volume; and is tortuous, in that flow at any point may move in any of a myriad of possible directions. Such a flow path is not fluid flow through an enclosed passage or conduit. Thus, use of a porous material does not equate to use of a capillary channel.

7. Consistent with this common definition of the term “channel,” the present specification also makes it clear that the term “capillary channel” does not equate to porous materials, such as the materials employed in the ‘268 patent cited by the Examiner in the Office Action. For example, the specification states on page 3 that the described devices do not use porous materials to control the flow of reagents through the device (lines 1-4); instead, the described devices use “novel capillary means, including channels” (lines 26-27). This clearly distinguishes porous materials from “channels.”

8. Thus, considering the pending claims in light of the foregoing discussion as to how one of ordinary skill in the art would interpret the term “capillary channel,” it is my opinion that the skilled artisan would readily acknowledge that the ‘268 patent does not disclose or otherwise teach a device with capillary channels. In claim 1 of the present application, the capillary channel comprises a first capillary region comprising a hydrophilic surface, and a second capillary region comprising a hydrophobic surface adjacent to this first region. In contrast, the ‘268 patent discloses a first and second layer formed from “a composite structure of porous materials” through which fluid flows. ‘268 patent, column 1, lines 63-64. The “porous members” (column 2, line 57) making up this composite structure are wholly different from a “capillary channel” of the present claims. Indeed, the specification indicates that it is problems with devices containing porous materials that the present specification hopes to avoid. *See, e.g.*, specification, page 3. This same distinction exists for those claims dependent from claim 1, and claims 13-17.

9. Claim 2 of the present application draws an even clearer distinction between the devices disclosed in the ‘268 patent and those of the present claims. Claim 2 refers to a device further comprising a third capillary region, where the hydrophobic surface of the second capillary region controls the rate of fluid flow into the third capillary region. This feature is not disclosed anywhere in the ‘268 patent. Instead, the ‘268 patent indicates that flow rates are controlled

through the use of impermeable barriers or slots (column 3, lines 66-68). These impermeable barriers or slots are not equivalent to the flow control regions of the present claims. This same distinction exists for those claims dependent from claim 2, and claims 6-12.

10. Furthermore, pending claims 3 and 12 indicate that the claimed devices delay fluid flow until the hydrophobic surface is rendered hydrophilic. Nothing in the '268 patent even suggests this possibility.

11. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements so made are punishable by fine or imprisonment or both under § 1001 of Capital Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Oct 16, 2003
Date

Kenneth F. Buechler
Dr. Kenneth F. Buechler